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The use of a novel type of distal protection system (FiberNet®) in the percutaneous management of saphenous vein graft disease

Zastosowanie nowego systemu protekcji dystalnej (FiberNet®) podczas angioplastyki pomostów żylnych

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Abstract

Percutaneous intervention in saphenous vein grafts is associated with a high risk of distal embolisation by plaque material, 'no flow' phenomenon and clinical complications such as myocardial infarction or death. According to randomised trial evidence, intervention in a degenerated vein graft should be performed using an embolic protection device (EPD), since this strategy significantly reduces periprocedural and 30 day adverse event rate. FiberNet® is a novel distal protection system with unique characteristics of a low crossing profile (0.031'' for vessel size 3.5–5 mm), 'cotton wool'-like three dimensional design and a small pore size (40 μm). The FiberNet® does not require a separate delivery sheath and self-achieves its optimal apposition to the vessel wall; the EPD system also contains a dedicated aspiration catheter. We present the use of FiberNet® in a 77 year-old patient who had undergone coronary artery bypass grafting 20 years ago and currently presented with CCS class III angina due to a significant stenosis of the saphenous vein graft to the marginal branch. The procedure involved the use of a novel mesh-covered stent (MGuard®) designed to 'trap' the plaque material between the stent and the vessel wall. It was technically successful and clinically uncomplicated, and the patient remains well six months later.

Key words: saphenous vein graft disease, embolic protection devices, mesh-covered stent

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INTRODUCTION

Atherosclerotic degenerative disease occurs in about 80% of saphenous vein grafts (SVG) 10 to 15 years after coronary artery bypass grafting (CABG) [1]. For this reason, 15 years after CABG, up to 30% of patients require re-revascularisation: either reoperation or percutaneous coronary intervention (PCI) [2]. SVG angioplasty is a high risk procedure but, overall, it is associated with better long-term survival than repeated surgery [3]. For many years, PCI of degenerated SVG has been associated with a risk of periprocedural myocardial infarction (MI) or death (as a result of distal embolisation) as high as 16.5% [4].

The introduction of embolic protection devices (EPD) was crucial in increasing the safety of degenerated SVG-PCI. The efficacy of EPD was first demonstrated in randomised trials such as SAFER [4] and FIRE [5], which showed a 40% fewer MI and deaths in the 30 day observation in comparison to interventions without EPDs. Current guidelines on PCI recommend the use of distal EPDs when technically feasible in patients undergoing SVG PCI (class I A according to ESC, class IB according to ACC) [6, 7]. Although current EPDs (distal-filters or the occlusion balloon, or proximal flow blockade) significantly reduce the risk of distal embolisation, they are not fully effective in capturing embolic particles (the residual embolisation risk is ≈ 10%) [8]. For this reason, new generations of EPDs and stents are being developed. One new stent type dedicated to SVG-PCI combines a stainless steel stent and a mesh cover. The cover is made

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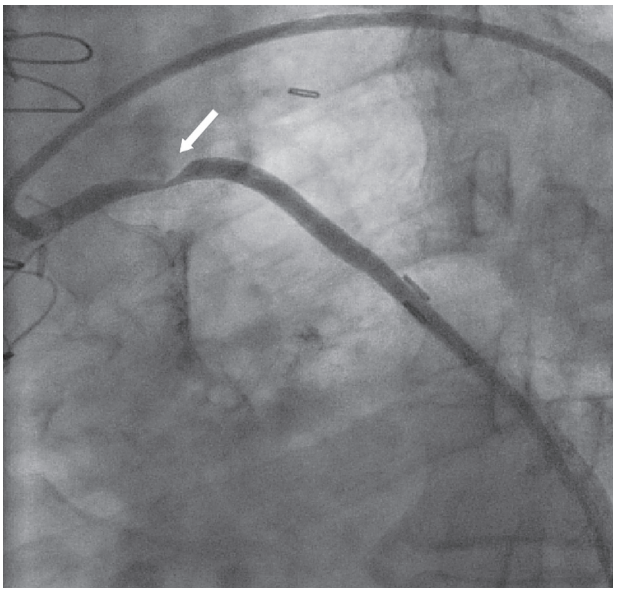

Figure 1. Critical stenosis of saphenous vein graft (arrow) implanted to the marginal branch

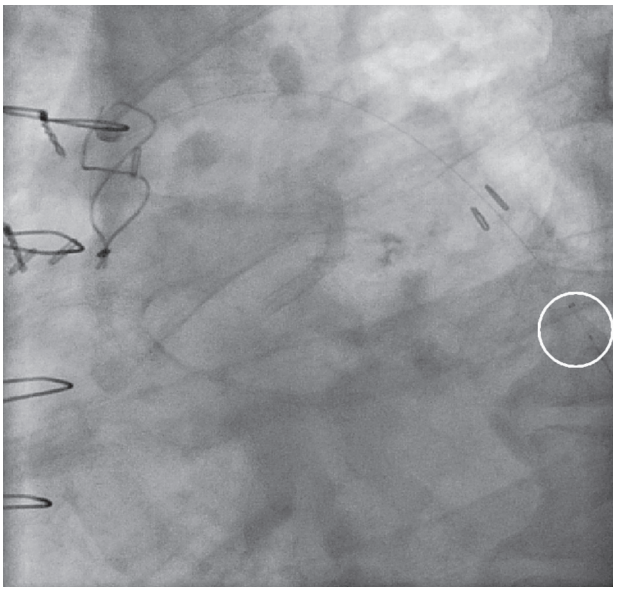

Figure 2. Aspiration with the dedicated FiberNet® aspiration catheter (circle)

of polyethylene terephthalate (PET) and has a mesh pore size of 150 × 180 μm. In a pilot study of SVG-PCI (mean SVG age of 14 years), using the mesh covered stent was associated with the risk of MI as a result of 'no flow' phenomenon in only 3.3% of patients, where EPDs were not used due to unsuitable graft anatomy [9].

We present the use of a novel distal protection EPD (FiberNet®) in PCI of a degenerated SVG. The procedure was performed in a patient 20 years after CABG and involved a mesh covered stent (MGuard®) implantation.

CASE REPORT

A 77 year-old patient with a 25-year history of MI was admitted in 1987 to our Department because of CCS class III angina. In 1990, the patient underwent CABG with two SVGs being implanted: one to the left anterior descending artery (LAD) and one to the marginal branch (Mg). Echocardiography showed a global ejection fraction of 50% with hypokinesis of the anterior and inferior wall. Coronary computed tomography angiography indicated a significant stenosis of the SVG to Mg in its proximal part, whereas the SVG to LAD was patent and appeared free of critical lesions. Native-vessel coronary angiography showed multivessel coronary artery disease: subtotal left main coronary artery stenosis and proximal LAD stenosis, a significant stenosis of circumflex artery, chronic total occlusion of first Mg and a subtotal stenosis in the proximal segment of the unprotected right coronary artery (RCA). Bypass graft catheter angiography confirmed critical stenosis in the proximal part of SVG (Mg) (Fig. 1). The SVG (LAD) was patent and it was not significantly diseased. The patient was scheduled for a two-stage percutanous coronary revascularisation. In the first stage, RCA-PCI with a drug eluting stent (Endeavor Resolute® 3.0 × 15 mm) implantation was performed uneventfully. Two weeks later, the patient was admitted for the SVG (Mg)-PCI. The SVG (Mg) ostium was intubated using a JR 4.0/6 F catheter. Due to the access anatomy, the SVG (Mg) stenosis was crossed with BMW 0.014" guidewire prior to introduction of the FiberNet® distal protection system. Then the device (FiberNet® 3.5–5.0 mm) was introduced with BMW 0.014" guidewire serving as a 'buddy wire' and placed distal to the lesion. Direct implantation of a MGuard® stent 4.0 × 15 mm (dilatation at 10 atm, post-dilatation at 12 atm) was followed by the 'no-flow phenomenon' (TIMI-1) in the treated vessel. The patient complained of severe retrosternal pain and ECG showed profound ST depression. While the flow was markedly impaired, several aspirations with the FiberNet® aspiration catheter were performed (Fig. 2). This led to restoration of normal (TIMI-3) flow in the SVG (Mg), while the open FiberNet® filter was still positioned distal to the treated lesion. The retrosternal pain resolved and the embolic protection device was removed. Final angiography showed a normal antegrade flow in the SVG (Mg) and in the marginal branch, and an optimal stent apposition (Fig. 3). There was macroscopic evidence of gross debris in the FiberNet® filter and in the aspirate. Myocardial necrosis markers remained normal (cardiac troponin I 0.06 ng/mL, CK 51 U/L, CK-MB 18 U/L). Six months later, the patient remains free of angina.

DISCUSSION

The use of conventional EPDs in SVG-PCI leads to a significant reduction of PCI-associated major adverse events (9.4% *vs* 16.5%, p = 0.004) [4]. No major clinical outcome differences were found between various protection systems [8]. However, both proximal and distal current EPDs have important limitations. For instance, proximal lesion location (as in the presented case, Fig. 1) precludes the use of a proximal EPD. Flow cessation with proximal or distal occlusion per se

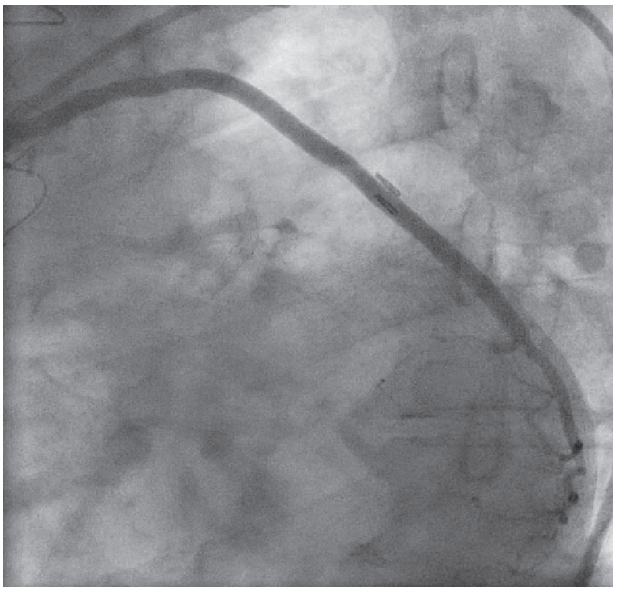

Figure 3. Final result of the procedure, after the FiberNet® filter retrieval

induces ischaemia and significantly limits the target lesion/ /vessel visualisation which can affect appropriate stent positioning. However, proximal or distal balloon occlusion devices allow effective aspiration of even small debris. Distal filters allow maintained flow during the PCI but require a suitable landing zone; at least a 30 mm long atherosclerosis-free segment [8]. The currently used filters have a pore size of 80––140 μm [8] that still permits embolisation with debris fragments below the pore size. Importantly, in more than one in four degenerated SVGs, no current protection system can be applied for anatomical reasons [8]. Since the complication rate of current EPD-protected SVG-PCI remains significant ($\approx$ 10%), new protection systems and dedicated stent types are being developed. The novel embolic protection system FiberNet® was designed to combine the advantages of the currently used embolic protection devices. The filter is made of PET fibers with a unique three-dimensional design. The FiberNet® does not impair the antegrade blood flow during PCI and it captures embolic particles as small as 40 μm. Importantly, the FiberNet® is a low profile device (crossing profile for a 3.5–5 mm vessel size is only 0.031″). Recently, the use of FiberNet® in carotid angioplasty (the EPIC study) has demonstrated the high efficacy of this device (death/ /stroke/MI: 4.2% in symptomatic and 2.7% in asymptomatic patients) [10].

The evidence indicates that combining the FiberNet® embolic protection system with a mesh covered MGuard® stent implantation may have been crucial for the safety of the described procedure. This strategy allowed an uncomplicated PCI of a degenerated, 20 year-old SVG. Despite the moderate stent post-dilation pressure (12 atm), there was a fully symptomatic 'no flow' syndrome (most probably due to the high embolic load in the filter and the vessel segment proximal to it) that was resolved through aspiration of the debris. At present, FiberNet® is the only EPD combing distal filtering with aspiration. While there is no doubt that EPDs should be routinely used during PCI of degenerated SVG whenever it is technically feasible [4–8], optimal selection of EPDs for SVG-PCI should, similarly to carotid artery stenting with EPD [11, 12], involve choosing the EPD that best suits the target SVG anatomy and lesion morphology [8].

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